DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12 FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Barry J. Cadden, Owner

FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	697 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

1. On 10/02/2012, we observed approximately eighty-three (83) vials out of a bin containing 321 vials of methylprednisolone acetate (preservative free) 80mg/mL from Lot #08102012@51 (shipped to customers between 8/17/12 – 9/25/12 per firm distribution data), a sterile injectable drug, to contain what appeared to be greenish black foreign matter. Seventeen (17) vials from the same bin of methylprednisolone acetate (preservative free) 80mg/mL were observed to contain what appeared to be white filamentous material.

The sterility sample taken by the firm consisting of one 5ml vial of bulk formulated methylprednisolone acetate (preservative free) from lot 08102012@51 resulted in a sterile result (lab analysis started 8/14/12 and reported 8/28/12). However, the FDA analysis of FDA Sample #693965, consisting of methylprednisolone acetate (preservative free) 80mg/mL, 1mL filled vials, from Lot #08102012@51 collected from the firm, confirmed the presence of viable microbial growth in 50/50 vials tested. One vial examined microscopically showed fungal morphological features.

2. Although the formula worksheets state the raw materials are sterile, the Pharmacy Director stated that the firm uses non sterile active pharmaceutical ingredients (APIs) and raw materials, with the exception of sterile water for injection, to formulate injectable suspensions including but not limited to preservative free methylprednisolone acetate and triamcinolone. During the inspection, we observed that the labeling for the methylprednisolone API and additional raw materials did not indicate that they were sterile. Samples were collected for analysis of the non-sterile API and 3 additional raw materials used in the formulation of methylprednisolone acetate. The firm provided no documentation or evidence to support that the steam autoclave cycle used to sterilize suspensions formulated using non-sterile API and raw materials is effective.

3. The firm's environmental monitoring program yielded the following microbial isolates (bacteria and mold) within Clean Room 1 and Clean Room 2, used for the production of sterile drug products, between January 2012 and September 2012. Firm personnel stated that the firm shuts off the air conditioning from 8:00 pm to 5:30 am nightly in the Clean Room.

Table #1: Surface Samples from ISO 6 (Class 1,000) Rooms
Alert: 3 CFU Action: 5+ CFU

Location	Result Bacteria	Result Mold	Date
Main Clean Room			
CRBin1 (polymyxin under station 1)	0	1	2/16/12
4 FLR (near hood 5)	10*	2*	2/23/12
2 FLR (near hood 3)	3	1	3/8/12

BLACK LINE ON ORIGINAL - NOT A REDACTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Thomas W. Nerney, Investigator	Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	11/24/13

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Location	Result Bacteria	Result Mold	Date
4 FLR (near hood 5)	2	2	3/15/12
Table 2	0	1 mold (¾ of plate)*	3/29/12
1 FLR (near hood 1)	One hair with growth around it		3/29/12
4 FLR (near hood 5)	OG*	0	4/5/12
CRBin1(inside big uline bin with omnipaque 240)	1	1	6/13/12
3 FLR (near horiz hoods)	OG*	0	6/13/12
3 FLR (near horiz hoods)	1	2	6/28/12
CRBin2 (front of tetracaine Hcl powder container)	0	OG mold*	7/5/12
Pass thru	0	1 small mold	7/26/12

Note: (*) indicates result over action level; OG indicates over growth

Table #2: Surface Samples of ISO 7 (Class 10,000) Rooms
Alert: 5 CFU Action: 7+ CFU

Location	Result Bacteria	Result Mold	Date
Gown Room (Clean Room 1)			
8 FLR (GR/near hooks)	23*	0	2/16/12
GRmisc2 (vent arms)	13*	1*	2/16/12
GRmisc2 (empty plastic bag in empty bin)	19*	0	2/23/12
GRmisc1 (vent arms behind hand washer)	27*	0	2/23/12
7 FLR (gown room/entrance)	2*	11*	2/23/12
8 FLR (gown room/near hooks)	11*	4*	2/23/12
7 FLR (gown room/entrance)	0	1	3/1/12
WallGR2 (windowsill side to MR)	18*	0	3/1/12
8 FLR (gown room/near hooks)	12*	0	3/1/12
GRmisc2 (vent grids)	16*	2*	3/1/12
7 FLR (gown room/entrance)	3	2	3/8/12
8 FLR (gown room/near hooks)	3	2	3/8/12
7 FLR (gown room/entrance)	3	3	3/15/12
8 FLR (gown room/near hooks)	0	2	3/15/12
8 FLR (gown room/near hooks)	16*	0	3/29/12

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Philip Kreiter, Investigator
Almaris N. Alonso, Microbiologist
Thomas W. Nerney, Investigator
Debra M. Emerson, Investigator

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Location	Result Bacteria	Result Mold	Date
GRmisc2 (floor under barrel against wall)	11*	0	3/29/12
8 FLR (gown room/near hooks)	10*	0	4/5/12
7 FLR (gown room/entrance)	0	1	4/5/12
GRmisc1 (rubber flap over wheel of rack)	9*	0	4/12/12
WallGR1 (window sill side to middle room)	9*	0	4/12/12
GRmisc1 (top of rack with bouffants)	12*	0	5/10/12
7 FLR (GR/entrance)	2	1	5/31/12
8 FLR (GR/near hooks)	19*	0	5/ 31/12
8 FLR (GR/near hooks)	0	13*	6/28/12
7 FLR (GR entrance)	3	3	6/28/12
GRmisc1 (bottom of bootie bin)	¾ of plate OG*	1*	7/26/12
GRmisc2 (bottom of mask bin)	plate ¾ overgrown*	0	7/26/12
8 FLR (GR/near hooks)	9*	0	7/26/12
GRmisc2 (front of 7-7.7 glove bin)	OG*	1*	8/2/12
GRmisc2 (loose bootie bin)	0	Plate ½ mold*	8/23/12
Middle Room (Clean Room 1)			
5 FLR (near crimp bench)	0	1	2/23/12
6 FLR (near sink bench)	0	3	2/23/12
6 FLR (near sink bench)	2*	11*	3/15/12
MRmisc1 (dh20 gallon)	1	1	5/10/12
Gown Room (Clean Room 2)			
Gown Room Flr	OG*	0	1/26/12
Gown Room Flr	0	1	3/1/12
Gown Room Flr	9*	0	8/9/12
Prep Room (Clean Room 2)			
Prep Room Flr	1	1	2/2/12
Misc #2 PR (top of radio)	0	1	2/7/12
Misc: PR (Calcium chloride bin)	1	1	4/4/12
Prep Room Flr	15*	2*	6/13/12

Note: (*) indicates result over action level; OG indicates over growth

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Table #3: Surface Samples of ISO 8 (Class 100,000) Rooms
Alert: 8 CFU Action: 10+ CFU

Location	Result Bacteria	Result Mold	Date
Prep Room (Clean Room 1)	[redacted]		
Misc. Prep room samples (shopping cart handle)	0	OG with mold*	1/6/12
Misc. Prep room samples (metal cart)	1	1	1/26/12
PR (carriage w/blue handle w/scratch marks)	3	1	2/2/12
PR (carriage w/blue handle w/x)	4	1	2/2/12
PR (outside of barrel)	16*	2*	3/1/12
9 FLR (PR) (near entrance)	1	7	3/8/12
PR (blue tamper evident caps, bin)	4	3	3/15/12
PRmisc2 (inside plastic cover to clear plastic bags)	OG*	0	4/5/12
9 FLR prep room (near entrance)	¾ plate OG*	0	4/5/12
10 FLR (PR) (under 2nd rack)	3	1	4/12/12
PR MISC 2 (top of lid of white container under rack)	1	1	5/24/12
10 FLR (PR) (back of room area)	OG*	0	5/24/12
10 FLR (PR) (back of room area)	0	3	5/31/12
9 FLR (PR) (entrance area)	OG*	0	6/15/12
10 FLR (PR) (back of room area)	20*	0	6/15/12
10 FLR (PR) (back of room area)	12*	0	6/28/12
9 FLR (PR) entrance area	4*	15*	6/28/12

Note: (*) indicates result over action level; OG indicates over growth

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Table #4: Air Sampling of ISO 6 (Class 1,000) Rooms

Location	Result Bacteria	Result Mold	Date
Middle Room (Clean Room 2)	[redacted]		
Middle room	0	1 big mold	5/29/12

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	[signatures]	Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	10/26/12

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Table #5: Air Sampling of ISO 7 (Class 10,000) Rooms
Alert: 5 CFU Action: 8+ CFU

Location	Result Bacteria	Result Mold	Date
Gown Room (Clean Room 1)			
Gown room	29*	1*	5/31/12
Gown room	11*	1*	6/28/12
Middle Room (Clean Room 1)			
Crimp Station	3	1	2/23/12
Prep Room (Clean Room 2)			
Prep room	0	1	5/2/12
Gown Room (Clean Room 2)			
Gown room	7*	3*	8/9/12

Note: (*) indicates result over action level

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Table #6: Surface and Air Sampling of ISO 5 (Class 100) Clean Room 2
No Action/Alert Levels specified by firm for ISO 5 (Class 100) areas.

Location	Sample Type	Result Bacteria	Result Mold	Date
Table 1 (near Horiz L & R hoods)	Surface	0	3	1/26/12
Table 1 (near Horiz L & R hoods)	Surface	1	1	5/2/12
Between Horiz L & Horiz R	Air	1	1	7/25/12

There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacteria and mold) from the facility.

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

4. The environmental monitoring procedure requires sampling via personnel touch plates taken upon completion of sterile compounding and prior to cleaning. Records from January thru September 2012 for Clean Room 1 and Clean Room 2 showed the following results inside production hoods:

Table #1: Clean Room 1 and Clean Room 2 Facility Personnel Touch Plates

Date	Isolates	Location	Product
1/3/12	OG with bacteria	Horizontal 1 (Clean Room 1)	Avastin
4/12/12	OG with bacteria	IT/Hood 3 (Clean Room 1)	Product not documented
6/15/12	1 bacteria, 1 mold	Horizontal 2A (Clean Room 1)	Ropiv/Ketor/Epi
6/21/12	2 bacteria	Horizontal R (Clean Room 2)	Product not documented
7/2/12	½ plate OG with bacteria	Horizontal L (Clean Room 2)	Product not documented
7/19/12	1 bacteria, 2 molds	Horizontal 2C (Clean Room 1)	Mafenide Acetate
7/31/12	2 bacteria	Horizontal 2A (Clean Room 1)	KCl/Lido/D5W
8/16/12	2 bacteria	Hood 3 (glovebox) (Clean Room 1)	Ace 20%, Ped Atropine

Note: OG indicates over growth

These results were not investigated and there was no identification of the isolates. There were no product impact assessments performed for any sterile products that were made in the hoods or gloveboxes on the days the samples were taken. In addition, the firm has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products.

5. The conditions listed below were identified during the inspection in areas used for the preparation, filling, and/or storage of sterile drugs products.

- On 10/04/2012, we observed condensation and what appeared to be tarnished discoloration on the interior surfaces (e.g. chamber) of the "(b) (4) autoclave", located in the firm's Middle Room (ISO 7). This autoclave is used for the steam sterilization of formulated bulk drug suspensions, including preservative free formulations of methylprednisolone and triamcinolone, which are intended for injection. Of note, this is the final sterilization step in the process for these products.

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- On 10/04/2012, we observed greenish yellow discoloration lining the interior surface of the viewing lens within the "Inside" autoclave, located in the firm's Middle Room (ISO 7). This is one of two tabletop autoclaves used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation of sterile drug products

- On 10/04/2012, we observed what appeared to be tarnished discoloration on the interior surfaces (e.g. chamber and trays) of the "Outside" autoclave located in the firm's Middle Room (ISO 7). Moreover, condensation was observed along the interior surfaces of the "Outside" autoclave to collect in a pool at the base of the chamber. This is one of two tabletop autoclaves used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation of sterile drug products.

- The firm is abutted to the rear and along the left parking area by a recycling facility that handles such materials as mattresses and plastics. On 10/02/2012, the area was observed to include large equipment (e.g. excavators and freight trucks) producing airborne particulates (e.g. dust). Rooftop units serving the firm's HVAC system were estimated to be located approximately 100 feet from the recycling facility.

- On 10/04/2012, we observed what appeared to be dark particulate and white, filamentous substances covering the louvers of an HVAC return located behind the "(b) (4) autoclave", located in the firm's Middle Room (ISO 7). This autoclave is used for the steam sterilization of formulated bulk drug suspensions, including preservative free formulations of methylprednisolone and triamcinolone, which are intended for injection.

- On 10/02/2012 and 10/04/2012, we observed yellow residue lining the rear return of Weigh Station 2 Hood and greenish residue lining the rear return of Weigh Station 3 Hood, both located in the firm's ISO 6 Clean Room. The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

- On 10/04/2012, we observed greenish residue covering the surface of the (b) (4) ceiling, exposed to the (b) (4) filter above, within Weigh Station 3 Hood located in the firm's ISO 6 Clean Room. The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

- On 10/04/2012, we observed what appeared to be tarnished discoloration on the interior surfaces (e.g. chamber and trays) of the (b) (4) located in the firm's Prep Room (ISO 8). This (b) (4) is used to sterilize equipment (e.g. beakers, spatulas, and spoons) used in the formulation of sterile drug products.

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CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

- On 10/04/2012, a boiler installed within approximately 30 feet of the entrance to the Prep Room (ISO 8) was observed to be leaking water into puddles. Moreover, wet floor surfaces around the boiler appeared to be soiled with thick white debris and thick black, granular material. Gaps were observed between sliding doors, located at the transition between the Prep Room (ISO 8) and the warehouse, despite being fully closed. This room is used for the preparation of equipment and includes the (b) (4)

- On 10/02/2012, the tacky mat located within the entrance of the Prep Room (ISO 8), at the transition to the warehouse, was observed to be brown and soiled. This room is used for the preparation of equipment and includes the (b) (4)

- On 10/04/2012, we observed cloudy discoloration on the (b) (4) barrier (b) (4), facing the ISO 6 Clean Room, and metal surfaces within the "Pass Thru," installed within the wall of the ISO 6 Clean Room. Moreover, the metal ledge, within the ISO 6 Clean Room, was observed to contain reddish-brown and cloudy substances. The firm utilizes the ISO 6 Clean Room to formulate and fill sterile preparations, including methylprednisolone.

- On 10/04/2012, we observed what appeared to be dark, hair-like discoloration along the gasket and crevices located at the bottom edge of the closed pass through installed within the wall of the ISO 6 Clean Room. The firm utilizes the ISO 6 Clean Room to formulate and fill sterile preparations, including methylprednisolone.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	10/26/12